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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/832,419 | 04/11/2001 | Gregory E. Gonye | BC1042 US NA | 9546 |

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E I DU PONT DE NEMOURS AND COMPANY
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| EXAMINER |
|---|
| MCKELVEY, TERRY ALAN |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1636 | 17 |

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/832,419 | GONYE ET AL. | |
| | Examiner | Art Unit | |
| | Terry A. McKelvey | 1636 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2 and 9-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 9-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5,6* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-2 and 9-13, "presence of chemicals" species in Paper No. 14, filed 8/19/02 is acknowledged. Applicant has canceled the claims totally drawn to non-elected inventions.

***Claim Objections***

Claims 2 and 9-13 are objected to because of the following informalities: the claims are drawn to encompass non-elected inventions or species, or depend on canceled claims. The claims should be amended to only read on the elected invention and species, and to remove the dependence on canceled claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point

out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 9, the use of "wherein organism is selected from …" renders the claims vague and indefinite because it is unclear which organism is being referred to because of the lack of a proper article in front of "organism" and there is no positive antecedent basis for "organism" in claim 1 because no organism is indicated in claim 1.

Regarding claim 10, there is no positive antecedent basis for "the prokaryote" and thus the claim is vague and indefinite. It appears that the plural "prokaryotes" was intended; amending the claim to properly refer to the plural would be remedial (which also would probably require amending claim 11 too if enteric bacterium is also made plural).

Regarding claim 12, there is no positive antecedent basis for "the reporter gene or reporter gene complex" and thus the claim is vague and indefinite.

Regarding claim 13, there is no positive antecedent basis for "the genomic nucleotides sequence" and thus the claim is vague and indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ashby et al (applicant supplied reference, U.S. Patent No. 5,569,588).

Ashby et al teach a method of detecting reporter gene product signals from each of a plurality of different, separately isolated cells of a target organism, wherein each of said cells contains a recombinant construct comprising a reporter gene operatively linked to a different endogenous transcriptional regulatory element (e.g. promoter) of said target organism such that said transcriptional regulatory element regulates the expression of said reporter gene, wherein said plurality of cells comprises an ensemble of the transcriptional regulatory elements of said organism sufficient to model the transcriptional responsiveness of said organism to a drug, contacting each said cell with a candidate drug, detecting reporter gene product signals from each of said cells

before and after contacting each of said cells with said candidate drug to obtain a drug response profile, wherein said drug response profile provides an estimate of the physiological specificity or biological interactions of said candidate drug (column 1).

This reference teaches an ensemble of reporting cells for use in the methods that comprises as comprehensive a collection of transcription regulatory genetic elements as is conveniently available for the targeted organism so as to most accurately model the systemic transcriptional response. Suitable ensembles generally comprise thousands of individually reporting elements; preferred ensembles are substantially comprehensive, i.e. provide a transcriptional response diversity comparable to that of the target organism. Generally, a substantially comprehensive ensemble requires transcription regulatory elements from at least a majority of the organism's genes, and preferably includes those of all or nearly all of the genes. We term such a substantially comprehensive ensemble a genome reporter matrix. It is frequently convenient to use an ensemble or genome reporter matrix derived from a lower eukaryote or common animal model to obtain preliminary information on drug specificity in higher eukaryotes, such as humans (column 2).

Ashby et al teach an application of the genome reporter matrix in antibiotic and antifungal discovery. They teach that the genome reporter matrix offers a new tool to solve the problem of finding pharmaceutical targets in fungi that are specific to the fungus. Specifically, all molecules that fail to elicit any response in the Saccharomyces reporter are collected into a set, which by definition must be either inactive biologically or have a very high specificity. A reporter library is created from the targeted pathogen such as Cryptococcus, Candida, Aspergillus, Pneumocystis etc. All molecules from the set that do not affect Saccharomyces are tested on the pathogen, and any molecule that elicits an altered response profile in the pathogen in principle identifies a target that is pathogen-specific (column 5). This teaching reads on having assembled two genome-wide scale collections (because the reference teaches that these, which they call genome reporter matrix, are used in this particular method), perturbing each collection (both the Saccharomyces reporter collection and an additional fungus reporter collection) by adding the presence of a chemical (the elected species) to each collection. The response is measured from both reporter collections and analyzed to identify patterns of similarities and differences, as shown by the reference teaching that any

molecule that elicits an altered response profile (which is a pattern of similarities when not altered, and a pattern of differences when altered) in the pathogen in principle identifies a target that is pathogen. Determination of altered response profiles between the two reporter collections determines (differences and similarities of) gene function between the two organisms. Thus, the method steps of the claimed invention are taught by the cited reference.

This reference also teaches one embodiment of the method in which the reporter gene used is lacZ, and that a wide variety of reporters known in the art can be used, such as green fluorescent protein, lacZ, etc (column 7). The nucleotide sequence of Saccharomyces is over 50% known, because the whole genomic sequence is known in the art.

The genome reporter matrix taught by Ashby et al reads on genome-registered collections because it is a set of strains containing reporter gene fusions to at least a majority of all known or predicted promoter regions. Although Ashby et al do not specifically indicate that the genome reporter matrix has been mapped by homology to the nucleic acid sequence of the genome of the organism, Ashby et al teach that the ensemble of strains is comprehensive (corresponding to a majority of the organism's genes, each of which is different from the others in

the ensemble). "Mapping by homology" is merely acquiring homology information concerning the clones in the collection, which does not alter the structure of the collection, and thus a genome-registered collection has no structural difference from a collection that is not genome-registered. Accordingly, the genome reporter matrix taught by Ashby et al has the same structure as a genome-registered collection as claimed. And, because the same method steps, using the same products, are taught by the cited reference, the teachings of Ashby et al anticipates the claimed invention.

***Conclusion***

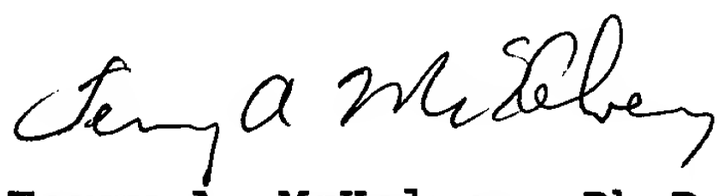
No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



**Terry A. McKelvey, Ph.D.**
**Primary Examiner**
**Art Unit 1636**

February 24, 2003